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10/578,340	03/06/2007	Larry Lapanashvili	088790-000300US	6589

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EXAMINER

LAVERT, NICOLE F

ART UNIT	PAPER NUMBER
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4123

MAIL DATE	DELIVERY MODE
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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,340	Applicant(s) LAPANASHVILI, LARRY	
	Examiner Nicole F. LaVert	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/06/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because a) reference character “34” has been used to designate both the display and the electrocardiogram (pp 9, para 2), b) reference character “36” has been used to designate both the pulse generator and the processor [(pp 8, para 5) & (pp 10, para 2)] Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: The “...dotted lines...” represented by the reference number 98, is not shown (pp 23, para 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because a) the notation “LYP,” should be changed to “LVP,” (Figure 3), b) In respect to the section notated by “B” the reference numbers “ 98 ’ ” and “94” should be changed to “ 98 ” ” and “94 ’,” respectfully (Figure 3). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant’s use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The disclosure is objected to because of the following informalities: a) The status of the foreign application number WO 2001/13990A must be updated (pp 1, para 2), b) In respect to the phrase, "...in the curve 88..." the reference number "88" should be changed to "90," (pp 20, para 3), c) In respect to the phrase, "...into the computer 36..." the reference number "36" should be changed to "100," (pp 23, para 1). Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 15-17, 20-21, 22-24 & 27-28** are rejected under 35 U.S.C. 102(b) as being anticipated by Lapanashvili (WO 2001/13390 A).

For **claim 15**, Lapanashvili et al. discloses, an electrotherapy apparatus for applying electrical stimulation to a muscle or group of muscles of a person or other mammal (pp 8, para 3), wherein said electrical stimulation comprises electrical pulses, said electrical stimulation having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses [(pp 32, para 4) & (pp 33, para 1)] and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal (pp 19, para 2), said offset lying in a range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave (pp 14, para 2), wherein the electrotherapy apparatus is adapted to vary at least one of said amplitude, said pulse repetition frequency, said duration and said offset in accordance with a predetermined pattern stored in an associated microprocessor, or randomly in accordance with a random number generator, within pre-specified limits in the course of a treatment extending over many heart cycles, typically over more than 15 minutes, and from one heart cycle to the next or periodically or after a predetermined or randomly selected number of heart cycles [(pp 30, para 4) & (pp 31, para 1-2)].

In reference to **claim 16**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said amplitude variation amounts to a variation in peak voltage of said electrical stimulating pulses in a range from +10 V to -10 V from a nominal value selected in the range from typically 10 to 50 V (pp 27, para 1-2).

In reference to **claim 17**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said pulse repetition frequency lies in a range from 20 to 1000 Hz, and wherein said pulse repetition frequency can be varied within said range (pp 31, para 2).

In reference to **claim 20**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein said offset can lie within said range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave, and can be varied in this range (pp 14, para 2).

In reference to **claim 21**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 15 (pp 8, para 3), wherein a plurality of said parameters are simultaneously varied (pp 31, para 2).

For **claim 22**, Lapanashvili et al. discloses, a method for applying electrical stimulation to a muscle or group of muscles of a person or other mammal using electrotherapy apparatus (pp 8, para 3), wherein said electrical stimulation comprises electrical pulses, the electrical stimulation

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having parameters comprising at least some of an amplitude, a pulse repetition frequency, a duration of each pulse or group of pulses [(pp 32, para 4) & (pp 33, para 1)] and a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal (pp 19, para 2), said offset lying in a range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path lengths of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave (pp 14, para 2), wherein at least one of said amplitude, said pulse repetition frequency, said duration and said offset is varied in accordance with a predetermined pattern, or randomly, within pre-specified limits in the course of a treatment extending over many heart cycles (pp 31, para 2), typically over more than 15 minutes.

In reference to **claim 23**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said amplitude variation is selected to amount to a variation in peak voltage of said electrical stimulating pulses in a range from +10 to -10 V from a nominal value selected in the range from typically 10 to 50 V (pp 27, para 1-2).

In reference to **claim 24**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said pulse repetition frequency is selected to lie in a range from 20 to 1000 Hz, and wherein said pulse repetition frequency is varied within said range (pp 31, para 2).

In reference to **claim 27**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein said offset is selected to lie within said range from 5% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path length of a plurality of

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preceding heart cycles or of a representative R-R path length, before the predicted end of said T-wave up to 45% of the R-R path length of the preceding heart cycle, or of an average value of the R-R path length of a plurality of preceding heart cycles, or of a representative R-R path length, after the predicted end of the T-wave, and is varied in this range or in a smaller range (pp 14, para 2)

In reference to **claim 28**, Lapanashvili et al. discloses, a method in accordance with claim 22 (pp 8, para 3), wherein a plurality of said parameters are simultaneously varied (pp 31, para 2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 18-19 & 25-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapanashvili et al. (WO 2001/13990 A) in view. Minogue et al. (US 20020058972 A1).

Lapanashvili et al. shows all the features of the instantly claimed invention as discussed above.

Lapanashvili et al. fails to disclose intervals of pulse duration ranges within .1 ms to 600ms and .1 ms to 60ms.

Minogue et al. teaches the duration of pulses of each pulsed signal varied between 50 microseconds and 1000 microseconds or between 5 milliseconds and 1000 milliseconds [0146].

It would have been obvious to one of ordinary skill in the electrotherapy art to have modified Lapanashvili et al. with the use of durations of pulses of each pulsed signal varied between 50 microseconds and 1000 microseconds or between 5 milliseconds and 1000 milliseconds, as taught by Minogue et al., in order to for manual independent varying of the magnitude of the pulses [Minogue, 0147].

In reference to **claim 18**, Lapanashvili et al. in view of Minogue et al. teaches, an electrotherapy apparatus in accordance with claim 15 (Lapanashvili, pp 8, para 3), wherein said pulse duration lies in the range from 0.1 ms to 600 ms and can be varied in this range [Minogue, 0146].

In reference to **claim 19**, Lapanashvili et al. in view of Minogue et al. teaches, an electrotherapy apparatus in accordance with claim 15 (Lapanashvili, pp 8, para 3), wherein an interval between successive pulses lies in a range from 0.1 ms to 50 ms and can be varied in this range [Minogue, 0146].

In reference to **claim 25**, Lapanashvili et al. in view of Minogue et al. teaches, a method in accordance with claim 22 (Lapanashvili, pp 8, para 3), wherein said pulse duration is selected to lie in the range from 0.1 ms to 600 ms or smaller and is varied within this range or in a smaller range [Minogue, 0146].

In reference to **claim 26**, Lapanashvili et al. in view of Minogue et al. teaches, a method in accordance with claim 22 (Lapanashvili, pp 8, para 3), wherein an interval between successive pulses is selected to lie in a range from 0.1 ms to 50 ms and is varied in this range or in a smaller range [Minogue, 0146].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole F. LaVert whose telephone number is 571-270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N.F.L

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123